



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Food and Drug Administration
Rockville MD 20857

May 16, 2003

The Honorable Patrick Leahy
United States Senate
Washington, D.C. 20510-6275

Dear Senator Leahy:

Thank you for your March 28 letter to Secretary Tommy Thompson regarding the Food and Drug Administration's (FDA or the Agency) prior notice proposed rule. The Secretary has asked me to respond on his behalf.

FDA's prior notice proposed regulation, which published in February 2003, would require U.S. purchasers or U.S. importers or their agents to give FDA prior notice before importing food. As you know, this regulation is required under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). You expressed concern that the proposed requirement for submitting pre-assigned U.S. Customs Service entry numbers may result in limiting the ports of entry between Canada and Vermont for shipments arriving by truck.

As you may know, the prior notice section of the Bioterrorism Act specifically states, "Nothing in this section may be construed as a limitation on the port of entry for an article of food." Under the statute, FDA's proposed regulation is not intended to act as a limitation on the port of entry for food shipments coming into the United States. FDA has proposed requiring the U.S. Customs entry or other identification number because we believe it is necessary for the accurate identification of the article for inspection. We also believe this information is critical for matching the prior notice to the corresponding U.S. Customs entry, or other identification, to assess the adequacy of the prior notice when the article arrives.

The Agency has received many comments on the prior notice proposed rule. Now that the 60-day comment period has ended, we are in the process of analyzing the comments. We appreciate your views and those of your constituents and we assure you that all comments received on this issue will be carefully considered. We are sending your letter to the docket, so it can be included as part of the public record on this important issue. Rest assured, the

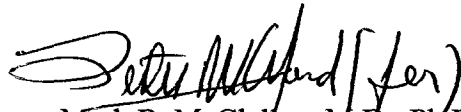
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Agency will carefully consider your concerns, including whether a U.S. Customs entry number on the FDA prior notice form could have the unintended effect of limiting the port of entry for food shipments entering the United States.

Thank you for your letter and for your continued interest in FDA's food safety and security activities.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark B. McClellan" with a stylized flourish at the end.

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs